Section 5. 510(k) Summary

510(k) Owner
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FDA Contact
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OCT 07 2013

Date Summary Prepared: June 12, 2013

Device Names

Trade Names:	CinchLock Knotless Suture Anchor NanoTack Suture Anchor 1.4mm
Common Name:	Bone Anchor
Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation number:	21 CFR 888.3040
Product Code:	MBI

Predicate Devices

Smith and Nephew BioRaptor 2.3PK Suture Anchor – K071586

Device Description
The Pivot Suture Anchors which are part of this expanded indications submission are as follows:
Pivot CinchLock Knotless Suture Anchor
Pivot NanoTack Suture Anchor 1.4mm

These anchors are non-degradable suture anchors manufactured from PEEK-OPTIMA® LT1 polymer. The CinchLock and NanoTack Anchors are attached to / pre-assembled to a stainless steel Inserter. Non-degradable ultra-high molecular weight polyethylene (UHMWPE) blue co-braid #1 suture is provided in the sterile package with the CinchLock Knotless Suture Anchor and Inserter. The Pivot NanoTack Suture Anchor incorporates

K131769

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a non-degradable ultra high molecular weight polyethylene (UHMWPE) blue co-braid #1 suture. The CinchLock Knotless Suture Anchor and NanoTack Suture Anchor 1.4mm devices are provided as a single use sterile devices.

Intended Use

The CinchLock Knotless Suture Anchor and the NanoTack Suture Anchor 1.4mm are intended for the fixation of soft tissue to bone in the hip, shoulder, foot/ankle, hand/wrist, elbow, and knee. Please see individual indications for use statements.

Summary of Technological Characteristics

The technological characteristics of the Pivot anchors included in this submission remain identical to those initially submitted in the prior Pivot 510(k) submissions. The main difference between the original submissions and this 510(k) submission is the addition of indications for use. The predicate device with the expanded indications is the Smith & Nephew BioRaptor 2.3PK Suture Anchor – K071586.

Summary of Performance Testing

The performance testing conducted demonstrates that the insertion and fixation properties of the CinchLock Knotless Suture Anchor and the NanoTack Suture Anchor 1.4mm are substantially equivalent to the predicate device.
Pre-clinical testing includes insertion strength, anchor strength, suture strength, and biocompatibility testing.

Summary of Substantial Equivalence

Based upon the indications for use, technological characteristics, and comparison to the predicate device, the CinchLock Knotless Suture Anchor and NanoTack Suture Anchor 1.4mm are substantially equivalent to the predicate device, including the expanded indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 7, 2013

Pivot Medical, Incorporated
Mr. Jon Cook
Director, Regulatory Affairs and Quality Assurance
247 Humboldt Court
Sunnyvale, California 94089

Re: K131769
Trade/Device Name: CinchLock™ Knotless Anchor
NanoTack® Suture Anchor 1.4mm
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 8, 2013
Received: July 9, 2013

Dear Mr. Cook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4. Indications for Use

510(k) Number (if known): K131769

Device Name: NanoTack® Suture Anchor 1.4mm

Indications for Use:

The NanoTack® Suture Anchor, previously cleared under 510(k) K110473 and K130351, is intended for fixation of soft tissue to bone in the hip, shoulder, foot/ankle, hand/wrist, elbow, and knee, in the following procedures:

Hip
Hip capsule repair
Acetabular labrum reattachment

Shoulder
Capsular stabilization
- Bankart repair
- Anterior shoulder instability
- SLAP lesion repairs
- Capsular shift or capsulolabral reconstructions

Acromialavicular separation repairs
Deltoid repairs
Rotator cuff tear repairs
Biceps tenodesis

Foot and Ankle
Hallux valgus repairs
Medial or lateral instability repairs/reconstructions
Achilles tendon repairs/reconstructions
Midfoot reconstructions
Metatarsal ligament/tendon repairs/reconstructions
Bunionectomy

Elbow, Wrist, and Hand
Biceps tendon reattachment
Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair

Knee
Extra-capsular repairs
- Medial collateral ligament
- Lateral collateral ligament
- Posterior oblique ligament

Patellar realignment and tendon repairs
- Vastus medialis obliquous advancement

Iliotibial band tenodesis

Prescription Use ___X___ AND / OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Orthopedic Devices

Section 4. Indications for Use (continued):

510(k) Number (if known): K131769

Device Name: CinchLock™ Knotless Anchor

Indications for Use:

The CinchLock™ Knotless Anchor, previously cleared under 510(k) K123651, is intended for fixation of soft tissue to bone in the hip, shoulder, foot/ankle, hand/wrist, elbow, and knee, in the following procedures:

Hip
Hip capsule repair
Acetabular labrum reattachment

Shoulder
Capsular stabilization
- Bankart repair
- Anterior shoulder instability
- SLAP lesion repairs
- Capsular shift or capsulolabral reconstructions

Acromialavicular separation repairs
Deltoid repairs
Rotator cuff tear repairs
Biceps tenodesis

Foot and Ankle
Hallux valgus repairs
Medial or lateral instability repairs/reconstructions
Achilles tendon repairs/reconstructions
Midfoot reconstructions
Metatarsal ligament/tendon repairs/reconstructions
Bunionectomy

Elbow, Wrist, and Hand
Biceps tendon reattachment
Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair

Knee
Extra-capsular repairs
- Medial collateral ligament
- Lateral collateral ligament
- Posterior oblique ligament

Patellar realignment and tendon repairs
- Vastus medialis obliquous advancement

Iliotibial band tenodesis

Prescription Use ___X___ AND / OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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